EXHIBIT 3

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April 21, 2015

Via Email Only – david.hampton@state.ma.us
J. David Hampton
Assistant Attorney General, Trial Division
Office of the Attorney General
Commonwealth of Massachusetts
One Ashburton Place
Boston, MA 02108

Re: *In re: New England Compounding Pharmacy, Inc., Products Liability Litigation Case No. 1:13-md-02419-RWZ*

Dear Mr. Hampton:

I am writing in response to your letter dated April 8, 2015, in which you object to the Notice of 30(b)(6) Deposition and *duces tecum* we issued to the Massachusetts Board of Registration in Pharmacy (the "Board"). As we previously discussed, we will hold a phone conference at 3:00 p.m. this afternoon to discuss your objections and the logistics of scheduling the 30(b)(6) deposition. Hopefully, this letter will resolve some of your objections and will help facilitate our conference call.

I. Objections to the Notice of 30(b)(6) Deposition

We are flexible with regard to the location and date of the 30(b)(6) deposition. However, under the current MDL scheduling order, there is a mid-June deadline for common issue discovery. We noticed the deposition to be taken at the Board's headquarters, but if you prefer an alternate location, please let us know. Also, please provide a date on which we can take the 30(b)(6) deposition. Numerous depositions are already scheduled in May and June, but we suggest May 20 or June 15 as possible dates if either works for you.

II. Objections to the *Duces Tecum*

A. Definitions

You asked us to clarify or define certain terms in the *duces tecum*. You stated in your letter that certain topics and documents requested of the Board are "more typically in the custody and control of the Massachusetts Department of Public Health." Therefore, to the extent possible, the term "Massachusetts Board of Registration in Pharmacy" should be construed to include the Massachusetts Department of Public Health.

"Traditional pharmacies" are pharmacies authorized to dispense prescription drugs. Traditional pharmacies may practice traditional compounding but do not engage in large scaled compounding or drug manufacturing.

"Traditional pharmacy compounder" refers to a pharmacist or pharmacy that practices traditional compounding.

"Traditional compounding" is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

"Large scale compounding" is compounding that utilizes commercial scale manufacturing, packaging, or testing equipment to produce large volumes of compounded products, including large-scale compounding in anticipation of receiving individual patient prescriptions.

An "outsourcing facility," as defined in the Drug Quality and Security Act,[1] is a facility at one geographic location that is engaged in compounding sterile drugs and has elected to register with the FDA, subjecting it to certain compounding constraints and inspection requirements.

"Conventional drug manufacturers" are pharmaceutical companies, regulated by the FDA, that are engaged in large-volume or industrial production of pharmaceutical drugs.

B. General Objections to the Notice and *Duces Tecum*

You objected to the Notice and *duces tecum* to the extent that they seek legal conclusions, privileged and confidential information, and information not reasonably calculated to lead to the discovery of admissible evidence.

These objections do not impact our ability to depose the Board's designee under Rule 30(b)(6). Federal courts have reached this same conclusion. In *SEC v. Kramer,* the United States District Court for the Middle District of Florida noted that it is highly unusual to prohibit the taking of a deposition altogether absent extraordinary

[1] 21 U.S.C. § 353b.

circumstances.[2] The *Kramer* court held that the need for protection usually cannot be determined before the examination begins, and that a party could move for a protective order if the need actually arises during a deposition.[3]

Regardless, if the Board contends that certain documents must be withheld on account of privilege, you may provide a privilege log. The privilege log will facilitate the evaluation of your objections and assertions of privilege. Certainly, *all* documents responsive to the subpoena are not privileged.

C. Undue Burden

You also objected to the Notice and *duces tecum* generally, on the ground that they are unduly burdensome. Under federal precedent, this argument fails.

In *Connaught Labs., Inc. v. SmithKline Beecham P.L.C.*, the United State District Court for the District of Delaware ordered the FDA to comply with the defendant's subpoenas over the FDA's objection that requiring its employees to testify would create an undue burden on the FDA.[4] A government agency provided notice under Rule 30(b)(6) "has the duty to name and produce one or more persons who consent to testify on its behalf as to matters known or reasonably available to the organization."[5] The government must comply with reasonable requests for information even when such requests "will entail significant effort on the part of the United States."[6] Like any litigant, the government must abide by the Federal Rules of Civil Procedure.[7]

The Board has already conducted its own investigation of, and reviewed documents in its possession related to, the meningitis outbreak. Producing these previously-reviewed documents will not be unduly burdensome on the Board. Additionally, in our *duces tecum*, we instructed that, to the extent requested documents have already been produced or are publicly available, you may simply state that to be the case and point us to where the documents are housed.

We are willing to discuss cost-sharing and cost-shifting as contemplated by Federal Rules of Civil Procedure 25 and 45. However, we will first need you to provide your estimated cost designating a knowledgeable witness for 30(b)(6) deposition testimony and producing the requested documents. If an agreement cannot be reached, the Federal Rules permit you to seek relief from the Court.

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[2] 778 F. Supp. 2d 1320, 1327 (M.D. Fla. 2011).
[3] *Id.* at 1327-28.
[4] 7 F. Supp. 2d 477, 480 (D. Del. 1998).
[5] *United States v. Magnesium Corp. of Am.*, No. 2:01-CV-40DB, 2006 U.S. Dist Lexis 87734 (D. Utah Nov. 27, 2006), at *15-16.
[6] *Id.*
[7] *SEC v. Collins & Aikman Corp.*, 256 F.R.D. 403, 414 (S.D.N.Y. 2009).

D. Specific Objections to the Notice

You objected to several specific paragraphs of the Notice on the ground that the requests are unlimited in time. Unless otherwise specified, the date range for all topics is January 2002 through September 2012.

Your other specific objections to the Notice of 30(b)(6) Deposition are addressed below by corresponding numbered paragraphs:

1. This topic is not overly broad. The Board inspected, regulated, and took enforcement action against NECC. This request asks you to designate a witness with knowledge of the legal or regulatory authority under which the Board took such action.

2. See the definitions provided above in paragraph (II)(A).

3. This topic simply covers the types of enforcement actions the Board may take against pharmacies.

5. This topic is not overly broad. Rather, it encompasses all complaints the Board received about NECC. The language "include, but are not limited to" prefaces a list of specific complaints about NECC and does not expand the scope of the requested testimony.

6. This topic is not overly broad because it only seeks (i) information regarding complaints about NECC that the Board received, and (ii) the Board's responses to those complaints. The topic is defined with reasonable particularity because it specifically refers to actions the Board took in response to "any and all complaints" about NECC other than those enumerated in Topic Number 5.

7. Again, this topic is not vague or ambiguous because it refers to any and all correspondence between the Board and NECC in response to complaints against NECC, except for those related to the complaints enumerated in Topic Number 5. To clarify, the Board may designate a witness with knowledge of all correspondence between the Board and NECC related to complaints against NECC.

8. Similarly, this topic is not vague or ambiguous because it refers to any and all communications between the Board and the FDA or other state pharmacy boards related to complaints against NECC. This topic relates to communications about complaints other than those enumerated in Topic Number 5. However, the Board may designate a witness with knowledge of all inter-agency communications related to complaints against NECC.

9. This topic addresses the Board's knowledge of NECC's operations and whether, based on that knowledge, the Board believed NECC was subject to FDA regulation in addition to regulation by the Board.

10. This topic is not overly broad because it only requests testimony about whether the FDA (i) shared information about NECC with the Board prior to the meningitis outbreak or (ii) suggested disciplinary action the Board should take against NECC.

12. "Since the outbreak" refers to any time after September 18, 2012. The language "or at any other times" does not make this topic overbroad. This topic only addresses whether the Board, at any time since September 18, 2012 has publicly stated that it should have taken disciplinary action against NECC but failed to do so.

13. This topic addresses (i) the extent to which the Board made information about NECC's failure to follow the law and industry standards publicly available prior to September 18, 2012, and (ii) what steps one of NECC's potential customers would need to take to obtain this information from the Board (e.g., access a public website, submit a FOIA request, etc.).

14. This topic is proper. If no potential NECC customers asked the Board for information about NECC's regulatory history, the Board may state that to be the case. Otherwise, the Board's designee should testify to what information the Board would have provided to a potential NECC customer, upon the customer's request, in 2011 or 2012.

15. This topic is not overbroad because it merely requests testimony about whether the Board warned any health care providers or other government agencies about the safety of NECC's products from 2002 to September 18, 2012.

16. This topic addresses the Board's findings following its investigation and inspection of NECC following the meningitis outbreak. The language "including (but not limited to)" does not broaden the scope of the request; rather it precedes a list of especially relevant findings highlighted in the Board's October 23, 2012 report.

17. Similarly, the language "including, but not limited to" does not broaden the scope of the request; rather it precedes a list of especially relevant subcategories related to the Board's knowledge of NECC's sister companies Ameridose and Alaunus Pharmaceuticals.

E. Specific Objections to the *Duces Tecum*

Your specific objections to the *duces tecum* are addressed below by corresponding numbered paragraphs:

2-4. "Public documents" is defined in Request Number 2, and "non-public documents" is defined in Request Number 3. Together, Requests 2-4 request all documents in the Board's possession about NECC. Certainly, the Board has a file related to NECC.

5. This request does not seek lay opinion testimony. Regardless of whether the Board's designee is considered a lay or expert witness, if the designee relies upon any treatises, scholarly journals, or other publications in giving his/her testimony, those publications should be produced in response to this request.

7. This request seeks the Board's policies, procedures, and training material related to the Board's regulation of, and enforcement actions taken against, compounding pharmacies. "Large-scale compounding pharmacies" are described in Request Number 7, and "large scale compounding" is defined above in Paragraph (II)(A).

8. "Any documents provided by NECC" to the Board is not overbroad or unduly burdensome. The Board's file on NECC most likely includes the documents sought by this request.

9. The phrase "related to" investigations of NECC is not vague or overly broad. This request seeks all documents the FDA provided to the Board with regard to (i) any complaint about NECC, (ii) information about NECC's failure to comply with the law or safety standards, and (iii) any enforcement action the FDA or Board took or planned to take against NECC.

III. Conclusion

We look forward to discussing this matter with you and resolving your objections to the Notice of 30(b)(6) Deposition and *duces tecum* issued to the Board. If you have any questions prior to our phone conference, please feel free to email or call us. Thank you for your cooperation.

Sincerely,

Jeremy Cain

Cc: C. J. Gideon, Jr.
Chris Tardio
Matt Cline